Four generations of quality—"Don't risk it" Accreditation standards and their role in quality assurance

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Introduction

This article reviews the two principal ISO 17000 series accreditation standards, namely ISO/IEC 17025[1] and ISO 17034,[2] their impact on the associated Quality Assurance, Testing or Calibration Laboratory and historically how these standards have evolved and continue to be implemented. In addition, this article discusses the role(s) of the ISO 9000 series and ISO 17000 series support standards within this controlled environment. It introduces the ISO Technical Committee, ISO/REMCO, which has supported this evolution/development. This Reference Material committee, now formally reorganised by ISO as TC 334, will be reviewed and discussed in the next article in the series. As we shall see, the "Don't risk it" message is a common theme through this review and is explicitly addressed in the latest revision of ISO/IEC 17025.

Background

The ISO Technical Committee responsible for the 17000 series standards, in all aspects of production and maintenance is ISO/CASCO – Conformity assessment, which is defined by its term of reference as follows.

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ISO/CASCO—Terms of reference

- To study means of assessing the conformity of products, processes, services and management systems to appropriate standards or other technical specifications.
- To prepare international guides and International Standards relating to the practice of testing, inspection and certification of products, processes and services, and to the assessment of management systems, testing laboratories, inspection bodies, certification bodies, accreditation bodies and their operation and acceptance.
- To promote mutual recognition and acceptance of national and regional conformity assessment systems, and the appropriate use of International Standards for testing, inspection, certification, assessment and related purposes.

ISO 9000

As detailed in the previous article ISO 9000 can essentially provide the quality management principles, required by the 17000 series standards. This is clearly demonstrated in the initial publication of ISO 17034, by the fact that an existing ISO 9000 quality management (QM) system can be used as an alternative to meet the QM chapter requirements of ISO 17034.

ISO 17000 series

Developed under the responsibility of ISO/CASCO, this series currently consists of 41 standards related to conformity assessment.

The three key standards in our area of interest are:

ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories is the main ISO standard used by testing and calibration laboratories. In common with other ISO quality standards, ISO/IEC 17025 requires continual improvement. Additionally, the laboratory will be expected to keep abreast of scientific and technological advances in relevant areas.

ISO 17034: General requirements for the competence of Reference Material producers.

ISO 17043: Conformity assessment—general requirements for proficiency testing. Given the explicit requirements and use of this standard within the proficiency testing arena, it will not be considered further within this article.

ISO/REMCO

There has always been and will continue to be collaboration between individual producers of reference materials (RMs). However, many years ago, RM producers recognised that the growing need by the analytical community for a number and variety of RMs as well as a need for the assurance of the quality of RMs called for collaboration at the international level. This has been

achieved through REMCO, the Council Committee on Reference Materials of the International Organization for Standardization (ISO), which celebrated its 25th anniversary in 2001. The evolution of this organisation and its conversion into the formal ISO Technical Committee, TC 334 – Reference Material in 2021 will be discussed in detail in the next article.

Accreditation

Accreditation is the formal recognition of the competence of a body or an organisation for a well-defined purpose. Accreditation of a laboratory to ISO/IEC 17025 involves assessment of the **technical competence and capability of the laboratory and its personnel**. In practice it is the procedure by which a laboratory is assessed to perform a specific range of tests or measurements. Specific areas examined include infrastructure and staff qualifications; in addition to checks that an adequate QM scheme is in place. The accreditation covers the range of materials tested or analysed, the tests performed, the method and equipment used, the accuracy or precision expected, and is specific to the facility and the test. This combination of technical and QM requirements is also found in ISO 17034, and will be discussed later.

1st Generation: the years between 1940 and 1975

Until the 1970s, most laboratories had used home-made test solutions or relied on the manufacturer to calibrate their instruments as part of routine maintenance. At the time, the only available references with internationally recognised and certified calibration values were those from National Measurement Institutes (NMIs) such as the National Institute of Standards and Technology (NIST) in the United States, whose products were trademarked as Standard Reference Materials (SRMs), but these were expensive and production capacity was limited. However, two important developments in this area of accreditation were the foundation of the Australian National Association of Testing Authorities (NATA) in 1947 and the New Zealand accreditation body TELARC in 1973. Obviously recognised within their own sphere of influence, the history of these organisations was only recognised on a worldwide basis with the formation of the International Laboratory Accreditation Cooperation (ILAC) in 1977.

2nd Generation: the years 1975 to 2000

ILAC first started as a conference, which was held on 24–28 October 1977 in Copenhagen, Denmark, with the aim of developing international co-operation for facilitating trade by promotion of the acceptance of accredited test and calibration results.

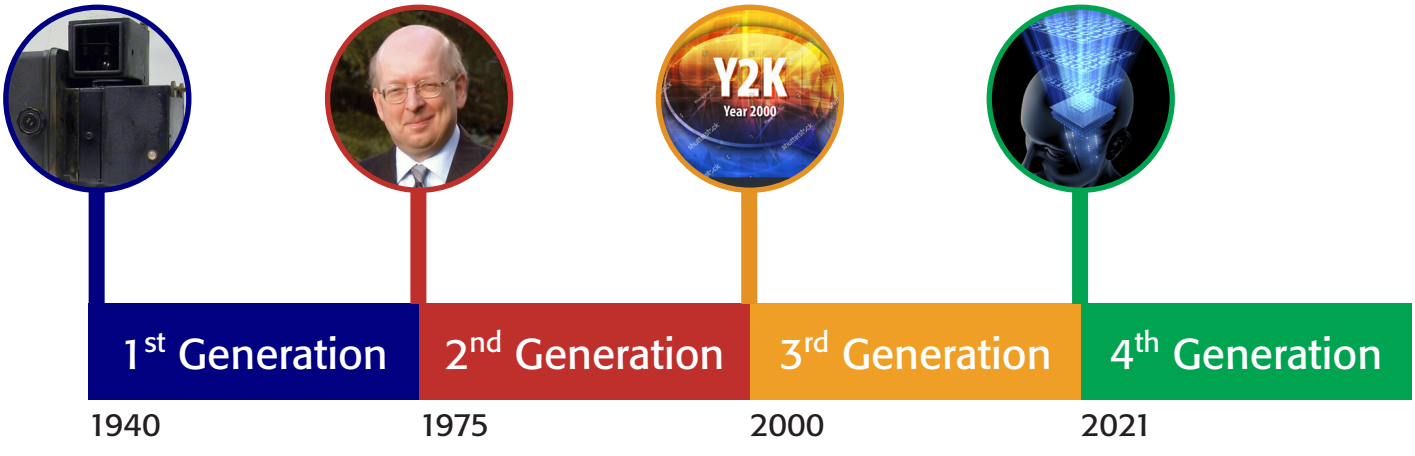
There then followed a relatively quiet period, until towards the end of this generation, a range of publications and events accelerated progress in this area, with the publication of key documents by the International Cooperation for Traceability in Analytical Chemistry (CITAC).[3,4]

Within these publications, and as the above organisation name suggests, a key and evolving concept is that of "Traceability". Traceability means different things to different people. If we look at the ISO International Vocabulary of Basic and General Terms in Metrology, ISO, 1993 definition:

"Traceability is the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties."

But this definition continues to evolve and has to be broadening into what this requirement means in an international marketplace. An excellent summary document is the CITAC paper on *Traceability in Chemical Measurement*.[5] This positioning paper clearly described the role that traceability has to play in a global marketplace, where ISO/IEC 17025 accreditation has the anchor role to play as the technical and Quality system standard implemented by the accreditation bodies.

In 1994, Accreditation in Europe is based on guidelines set out in the European Standard *General Criteria or the Operation of Testing Laboratories* EN45001 and the newly published (1990) ISO/IEC Guide 25 *General Requirements for the Competence of Calibration and Testing Laboratories*. The guidance was applicable to the performance of all objective measurements, whether routine, *ad hoc* or as part of research.



Most national laboratory accreditation schemes based their standards on these two documents. In the UK either EN 45001, or the identically worded BS7501, was used. This standard was implemented in the UK by The National Measurement Accreditation Service (NAMAS), which was formally established by the UK Government in 1985, and was administered by an Executive, based at the National Physical Laboratory (NPL) in Teddington. In May 1990, NAMAS contributed to a "memorandum of understanding", the Western European Laboratory Accreditation Co-operation (WELAC), which obtained mutual recognition agreements with the following countries:

Australia, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Hong Kong, Iceland, Ireland, Italy, Netherlands, New Zealand, Norway, Portugal, Spain and Switzerland.

NAMAS has subsequently become, in 1995, the United Kingdom Accreditation Service (UKAS).

In 1996, ILAC became a formal co-operation with a charter to establish a network of mutual recognition agreements among accreditation bodies.

In 2000, the 36 ILAC Full Members, consisting of laboratory accreditation bodies from 28 economies worldwide, signed the ILAC Mutual Recognition Arrangement (ILAC MRA) in Washington, DC, to promote the acceptance of technical test and calibration data for exported goods. The ILAC MRA for calibration and testing laboratories came into effect on 31 January 2001.

To achieve international recognition, the laboratories calibrating the references would need to be accredited to an international standard. ISO/IEC Guide 25 was first released in 1978 and covered "General requirements for the competence of calibration and testing laboratories". Later, the need to achieve compatibility with ISO 9001 led to a revision of the standard to ISO 17025, issued in 1999.

From a personal perspective this culminated in the accreditation of our (then Unicam) Calibration Laboratory to the new ISO/IEC 17025 standard for spectrophotometric transmittance measurements of Neutral Density optical filter glasses, by the then UK accreditation body (NAMAS).

As part of this process, we asked "How can instrument manufacturers assist with NAMAS compliance?"

The following five suggestions were given as the considered response from a co-ordinator and an assessor within the NAMAS organisation:

- User-friendly work instructions.
- Easy self maintenance.
- Advice on performance tests—what should you do to check?
- Filters traceable to International Standards (not own company standard).
- Ease of calibration.

These formed the basis for future developments in this area on a personal basis.

ISO/IEC 17025 was initially issued by the International Organization for Standardization in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 is more specific in requirements for competence and applies directly to those organisations that produce testing and calibration results and is based on somewhat more technical principles. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body.

There have been three releases, in 1999, 2005 and 2017, which have essentially evolved and revised the standard. The 2017 release is discussed (as the current version) in the 3rd Generation below.

3rd Generation: the years 2000 to 2020

So, as we enter this generation, ISO/IEC 17025 has "come of age" as the standard that provides the international aspect to any laboratory measurement process, and provides the control framework to assist the production of comparable measurements.

At this point it is interesting to review this extract from the ILAC news publication of 2000.

ILAC News, 2 November 2000
Signing of International Arrangement to Enhance Trade
An international arrangement, signed in Washington, DC, on 2 November 2000, will enhance the acceptance of technical data accompanying goods crossing national borders. The Arrangement, which involves 37 member bodies from 28 economies represented at the General Assembly of the International Laboratory Accreditation Cooperation (ILAC), means that goods tested in one country by a laboratory that is accredited under a signatory to the Arrangement, will be accepted by other signatories. This is a major step towards reducing or eliminating the need for re-testing of the goods by the importing country.

The Arrangement enters into force from 31 January 2001.

Belinda Collins, Chair of ILAC, noted the significance of the signing, "For many years, the retesting of goods by an importing country has been considered as a major technical barrier to trade. The World Trade Organization (WTO) identified such technical barriers as a major concern to world trade since the mid-1970s. Such barriers can not only add significant cost to goods entering a country, but can also delay, and in some cases prevent, the goods being accepted by foreign markets."

Dr. Collins further explained that "ILAC has been working towards overcoming these technical barriers for the last two decades by encouraging the development of regional recognition arrangements culminating in today's global recognition arrangement among representative bodies in each country. This will facilitate the acceptance of goods already tested by an accredited laboratory. Thus, goods tested in one country should enjoy easier access to foreign markets participating in the Arrangement."

The key to the Arrangement is the developing network of accredited testing and calibration facilities around the globe that are evaluated and recognized as being competent by specific authorities, known as laboratory accreditation bodies. These bodies are located in many economies and many of them participate in ILAC.

The following economies will participate in the Arrangement:

Australia, Belgium, Brazil, Canada, People's Republic of China, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, China, India, Ireland, Italy, Japan, Republic of Korea, The Netherlands, New Zealand, Norway, Singapore, South Africa, Spain, Sweden, Switzerland, Chinese Taipei, United Kingdom, United States of America, Vietnam.

A cornerstone of the new Arrangement is the utilization of existing or developing regional arrangements established in the Americas, the Asia Pacific region, Europe and Southern Africa. The bodies participating in these regional arrangements are responsible for maintaining the necessary confidence in accreditation bodies from their region that are signatories to the new ILAC Arrangement.

Mike Peet, Chair of the ILAC committee that developed the new Arrangement, explained the basis for the Arrangement's implementation by the international community: "Now that the Arrangement is in place, the next crucial step is for governments to take advantage of this Arrangement by using it to further develop or enhance trade agreements."

"There is now a firm foundation in place for manufacturers and exporters that have their goods tested by accredited laboratories to enjoy greater market access, less costs associated with re-testing, and overall greater competitiveness in global markets", he explained.

Established in 1977, ILAC is the peak international forum for the harmonization of laboratory accreditation procedures as a means of reducing technical barriers to trade, and the promotion of laboratory accreditation as a mechanism to enhance confidence in testing and calibration facilities, both domestically and internationally.

The ILAC MRA was then extended in October 2012 to include the accreditation of inspection bodies. In May 2019 it was further extended to include the accreditation of proficiency testing providers and in May 2020 for the accreditation of Reference Material producers. It is interesting that the message "Tested Once—Accepted Worldwide" is still being pursued, as shown below; although some may say that even 20 years later, we are still to fully achieve this "level field" across all countries and continents.

ISO/IEC 17025

The most significant changes between the 1999 and 2005 release were a greater emphasis on the responsibilities of senior management, explicit requirements for continual improvement of the management system itself, and communication with the customer. It also aligned more closely with the 2000 version of ISO 9001.

The 2005 version of the standard comprised five elements: Normative References, Terms and Definitions, Management Requirements, and Technical Requirements. Management Requirements are primarily related to the operation and effectiveness of the QM system within the laboratory. Technical Requirements include factors that determine the correctness and reliability of the tests and calibrations performed in the laboratory.

The 2017 version of ISO/IEC 17025 has modified this structure to be Scope, Normative References, Terms and Definitions, General Requirements, Structural Requirements, Resource Requirements, Process Requirements, and Management System Requirements. General Requirements and Structural Requirements are related to the organisation of the laboratory itself. Resource Requirements cite those issues related to the people, plant and other organisations used by the laboratory to produce its technically valid results. Process Requirements are the heart of this version of the standard in describing the activities to ensure that results are based on accepted science and aimed at technical validity. Management System Requirements are those steps taken by

Table 1. ILAC regional co-operations (taken from International Laboratory Accreditation Cooperation, ilac.org).

Recognised regional co-operation body		Scope of ILAC MRA recognition
	Inter American Accreditation Cooperation (IAAC)	Calibration: ISO/IEC 17025 Testing: ISO/IEC 17025 Medical Testing: ISO 15189 Inspection: ISO/IEC 17020 Proficiency Testing Providers: ISO/IEC 17043
	European co-operation for Accreditation (EA)	Calibration: ISO/IEC 17025 Testing: ISO/IEC 17025 Medical Testing: ISO 15189 Inspection: ISO/IEC 17020 Proficiency Testing Providers: ISO/IEC 17043 Reference Material Producers: ISO 17034
	Asia Pacific Accreditation Cooperation Incorporated (APAC)	Calibration: ISO/IEC 17025 Testing: ISO/IEC 17025 Medical Testing: ISO 15189 Inspection: ISO/IEC 17020 Proficiency Testing Providers: ISO/IEC 17043 Reference Material Producers: ISO 17034
	Arab Accreditation Cooperation (ARAC)	Calibration: ISO/IEC 17025 Testing: ISO/IEC 17025 Medical Testing: ISO 15189 Inspection: ISO/IEC 17020
	African Accreditation Cooperation (AFRAC)	Calibration: ISO/IEC 17025 Testing: ISO/IEC 17025 Medical Testing: ISO 15189 Inspection: ISO/IEC 17020

the organisation to give itself QM system tools to support the work of its people in the production of technically valid results. In addition, for the first time, there is an increased emphasis on the assessment (and measurement) of risk.

ISO 17034 (formerly ISO Guide 34)

The synergistic association of ISO 17034 with ISO/IEC 17025 is driven by the fact that invariably Certified Reference Materials (CRMs) produced under ISO 17034 will provide the traceability and uncertainty budget requirements for ISO/IEC 17025 accreditation, and in fact 17025:2017 explicitly states that where possible RMs produced under ISO 17034 should be used.

The role of ISO 17034 in the production of RMs that are "fit for purpose" has been frequently reviewed and discussed in several articles during this period in this publication.[6–14]

First published in 2000 as ISO Guide 34, alongside the evolution of ISO/IEC 17025, and in line with the already discussed expansion of laboratory accreditation during this period, its evolutionary path was directed by an ILAC resolution in 2004, which suggested that, after much debate, RM producers should be accredited to a combination of ISO Guide 34 and ISO/IEC 17025 accreditation, with the accreditation to ISO/IEC 17025 being used for the measured value(s) assigned in any CRM.

From a personal perspective, and working for an ISO/IEC 17025 accredited (in 2001) RM producer at the time, we were in involved in a UKAS pilot study into this process in 2005, which ultimately resulted in our accreditation to this "standard" in 2006.

As ISO Guide 34 was now being used for this process, the 2009 revision effectively revised and restructured the content of this guidance document into the required 17000 series standard in all but name, but as stated at the start of this article, the production and control of these standards fall under the auspices of ISO/CASCO. So how to solve this issue? The obvious way was for ISO to form a joint CASCO/REMCO sub-committee, tasked with the conversion of Guide 34 into 17034, and in 2016 this duly completed.

As a consequence, since that point in time our (Starna) Calibration Lab has been jointly accredited to both ISO/IEC 17025 and ISO 17034.

4th Generation: from 2021 forward

In 2021, our (Starna) accredited processes continue to evolve, in no small part accelerated by the global COVID-19 pandemic that we have all been experiencing and changing our working practices. In the context of this article, our UKAS full re-assessment to both standards was effectively and efficiently performed using a remote assessment, aided by the video technology we are now all familiar with.

From a standard maintenance perspective ISO 17034:2016 is due for review in 2021, and ISO/IEC 17025, next year in 2022. Given the extensive revision undertaken in producing these standards, it is unlikely that significant changes will occur—but we will of course keep you updated.

However, the same cannot be said for the ISO/REMCO structure and organisation, that has supported this interlinked science of laboratory accreditation and the use of RMs etc., and is now formed as ISO/TC 334.

For this reason, the next article in the series is dedicated to this ISO Technical Committee, and I welcome you back to this discussion in the near future, where we will continue the "Don't risk it" message.

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